REMARKS/ARGUMENTS

Reconsideration of the above-identified application is respectfully requested. Claim 6 has been amended to include the transitional phrase "consisting essentially of".

Claim Rejections – 35 U.S.C. § 103

Claims 6-7 and 9-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Raymond, U.S. Patent No. 5,693,462, in view of Massoudy *et al.* (J. Mol. Cell. Cardiol. 29, 535-544). Method Claim 6 has been amended to limit the claim to "consisting essentially of". Claims 7 and 9-10 depend from Claim 6. Claims 11-14 are directed to a medicament and are cast in "consisting essentially of" terms. It is well-settled that the transitional phrase "consisting essentially of" only opens the claims to the inclusion of ingredients that would not materially affect the *basic* and *novel* characteristic of the claim. *In re Herz*, 453 F.2d 549, 190 USPQ 461, 463 (CCPA 1976); M.P.E.P. §2111.03 [R-2].

The Examiner's position is that the Raymond patent teaches a preservation solution for preserving and storing organs such as a heart awaiting transplantation. The Raymond solution comprises:

(a) an isotonic solution;

(b) an amiloride-containing compound;

(c) adenosine; and

(d) water.

The active ingredients in the Raymond solution that materially affect its properties are the amiloride-containing compound and adenosine. This fact is clear from a reading of the Raymond specification. Raymond uses the amiloride-containing compound as one of the "active ingredients in the preservation solution" to inhibit Na+ - H+ exchange. *Col. 5, lines 32-35.* The other "active and material ingredient is adenosine. On the other hand, the active and material ingredient in the preservation solution of the claimed invention is cyclosporin A. The Examiner acknowledges that Raymond does not specifically teach the utilization of cyclosporin A in the composition or methods disclosed therein. The method of Raymond includes a medicament that requires the use of an amiloride-containing compound and adenosine. These products are

excluded in the claims of the subject invention by the use of the limiting transitional phrase. Therefore rendering Raymond non-obviating art.

The Examiner states that Massoudy *et al.* teaches that cyclosporin A acts as a cardio protective agent in ischemia and reperfusion (Abstract). Cyclosporin A, in concentrations of 0.8 μM in Krebs-Henseleit buffer, was shown to significantly prevent the loss of post-ischemic cardiac function (p. 537, col. 1, second full paragraph; p. 539, col. 2, first paragraph). The Examiner then argues that

> it would be obvious to one of ordinary skill in the art to add cyclosporin A to the composition of Raymond for the preservation of organs such as hearts, because (1) Raymond and Massoudy *et al.* are directed to an analogous art, namely both are directed to the preservation of organic function following ischemia and reperfusion; and (2) Massoudy *et al.* teach that cyclosporin A acts as a cardio-protective agent in ischemia and reperfusion. One would have been motivated to add cyclosporin A of Massoudy *et al.* to the composition of Raymond because of an expectation of success in improving the cardio protective characteristics thereof. *Office Action at page 3.*

The Examiner points to page 537 of Massoudy *et al.* to show that cyclosporin A is used to concentrations of 0.08 μM and 0.8 μM which is the effective plasma level required in patients after heart transplantation. Thus, the concentration chosen in the Massoudy study was very close to the reference levels in patients treated with CSA. It should be pointed out with respect to Claims 6 and 11 of the present application that the amount of cyclosporin A is present in an amount of about 2.5 μM to about 10 μM per liter of solution. The lower level CSA used in the present invention is **at least three times** the amount of CSA disclosed in Massoudy *et al.* The reason for that is the heart is being preserved prior to transplantation. Thus, the effects of cyclosporin A would be expected to be very different.

Even if Raymond and Massoudy *et al.* were to be properly combinable, that they would not teach the claimed invention because the medicament and method of Raymond would include the use of an amiloride-containing compound and the amount of CSA taught in Massoudy *et al.* is at least 1/3 lower that that claimed. Thus, in the situation, as this one is, one may certainly show nonobviousness by attacking references, from whatever art, that do not teach the invention

as claimed. Thereby, it is respectfully submitted that the claims are not obvious over Raymond in view of Massoudy *et al.* It is therefore respectfully requested that the claims now be allowed.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on June 16, 2005.

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